DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/04/11 has been entered.

Applicants' arguments, filed 05/04/11, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 9, 13, 17, 20, 25, 29, and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Costanzo (US 6,323,219).

Costanzo discloses preparing STI by grinding soybean in purified water and then filtered to remove the residual husk (Col 20, Example 11). Various depigmenting compositions comprising 1% w/w STI with preservatives and emulsifiers are disclosed

(cols 24-25, Example 17). Figure 13 discloses the STI compositions were administered to the skin of swine.

Note, any administration to a patient's skin of the instantly recited composition would appear to read on the instant method, given skin constantly regenerates and the step of administering the claimed composition will inherently reduce the risk of cutaneous tumor development.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 9, 13, 17-20, 25, 29, and 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Costanzo (US 6,323,219).

The reference is believed to be anticipatory as discussed above with regards to claims 1, 9, 13, 17, 20, 25, 29, and 34-37. For the sake of completeness of prosecution, purely arguendo and with regard to this particular ground of rejection only, however, it will be presumed that the prior art differs from the instant claims insofar as it does not specifically disclose administering to skin cells which have not yet been damaged by ultraviolet radiation. If that is so, it would have been obvious as unwanted skin pigmentation may occur in skin which has not been exposed to ultraviolet radiation and in such cases, the instantly claimed active steps would be met when treated.

With regards to the other claims, Costanzo is discussed above, but does not teach the length of treatment or administering to skin cells which do not have ultraviolet radiation induced DNA damage.

Costanzo further teaches the composition may be used to treat or prevent various conditions, including skin disorders (col 29 lines 34-50) where skin disorders include unwanted pigmentation or unwanted depigmentation (col 30 lines 15-17). Additionally, extended periods of treatment are disclosed, such as an eight week period to remove age spots (col 21 Example 13).

The instant prior art does not appear to provide sufficient specificity, i.e., involves too much "picking and choosing" to give rise to anticipation for these claims. *See*, Corning Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). That being said, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect.... the combination is obvious". KSR v. Teleflex, 127 S,Ct. 1727, 1740 (2007)(quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). Consistent with this reasoning, it would have obvious to have selected the various combinations of features claimed from within the prior art disclosure, such as administering to prevent unwanted pigmentation or unwanted depigmentation for an extended period of time, given patients will be exposed on an ongoing basis to triggers which cause the change in pigmentation, to arrive at the instantly claimed compositions. Further, where the method is directed to the prevention of changes in pigmentation, it would be obvious to administer the composition to patients who had yet to have ultraviolet caused damage.

Claims 1-4, 9, 13, 17-20, 25, 29, and 34-41 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Ryan (US 4,906,457, see IDS filed 07/12/04) in view of Maeda et al (JP 07010772, see IDS filed 07/12/04).

Ryan teaches the administration of a topical composition of protease inhibitors for reducing the risk of skin cancer caused by sunlight or other ultraviolet radiation (col 1 lines 35-40) where the composition preferably includes trypsin family of protease inhibitors derived from plants, such as from soybeans (col 1 line 67 spanning col 2 line 2 and claim 17).

Ryan does not specifically teach non-denatured Kunitz-type soybean trypsin inhibitors.

Maeda et al teaches trypsin inhibitors include soybean Kunitz-type trypsin inhibitors, which are rich in the composition disclosed by Maeda et al (English abstract).

Maeda et al does not teach the application of the preparation.

The primary reference specifically teaches the composition preferably includes plant derived trypsin inhibitors, an example of which is disclosed in the secondary reference. As such, one of ordinary skill in the art would find it obvious to use the trypsin inhibitor composition of the secondary reference because it shares this common activity with the composition of the primary reference, and thus would be reasonably predicted to provide corresponding therapeutic effects. See Daichi Sankyo v. Aptotex, 84 USPQ2d 1285 (Fed. Cir. 2007).

Applicants assert it is not proper for Examiner to rely on the claims to determine what a patent discloses. Further, Applicants assert the ‘457 patent fails to disclose any evidence that the disclosed protease inhibitors are useful in reducing the risk of skin cancer caused by sunlight or ultraviolet exposure. Applicants also assert that while the '457 patent teaches interrupting or reversing the biochemical processes in the skin, it does not teach inhibiting before the damage starts. Applicants then present Huang et al which teaches AP-1 is responsible for tumor progression action of UV light and pre-treatment of epidermal cells with soybean trypsin inhibitor had no significant inhibitory effect on UV-induced AP-1 activity. Applicants also assert the skilled artisan would not have selected a Kunitz-type soybean trypsin inhibitor where the articles of Huang et al, Kennedy, Yavelow and Messina teach trypsin is not related to cutaneous tumor development. Finally, Applicants disagree with Examiner’s position of unexpected results where liposomes are not required by the instant claims.

Examiner disagrees. First, a reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including non-preferred embodiments. MPEP 2123. As such, the ’57 patent teaches and discloses the use of trypsin inhibitors, where the entire disclosure (which includes the claims), specifically discloses trypsin inhibitors. Examiner notes that while BBI and potato inhibitor 1 families are specifically disclosed, the prior art is not limited to only the preferred embodiments.

Second, no evidence is required which suggests that protease inhibitors may be used to reduce the risk of skin cancer caused by sunlight or ultraviolet exposure. Where the claimed method is directed to reducing the risk of cutaneous tumor development, it

would appear that any application would produce the desired effect. The fact that a patient may already have a cutaneous tumor does not negate the fact that another cutaneous tumor could be prevented from the application.

Third, Huang et al is not applicable as the reference focuses on AP-1 activity, whereas the instant rejection is made with respect to a broader teaching which does not limit the discussion to specific mechanisms. So while soybean trypsin inhibitors may not have had an effect on AP-1 activity, it does not mean they did not have an effect on another mechanism which was related to cutaneous tumor development.

Fourth, while the references of Huang et al, Kennedy, Yavelow and Messina do not direct the skilled artisan to the use of a trypsin inhibitor, Examiner notes the primary reference specifically teaches contrary to such assertions. As such, the skilled artisan would be motivated to select a trypsin inhibitor not based on knowledge in the art, but based on the prior art reference which teaches their use.

Finally, with regards to unexpected results, Examiner notes that the percentage of mice with tumors decreased for every treatment compared to no treatment. At 21 weeks, while the soymilk treatment reduced the percentage to 83%, heated soymilk and BBI also reduced the percentage of mice with tumors to 90%. Where the change is from 90% to 83%, it is unclear if the results are unexpected or simply due to the combination effect of the combined protease inhibitors. Where the primary reference teaches administering a number of protease inhibitors, the skilled artisan would expect an increase in efficacy where more than one effective protease inhibitor was administered.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BENJAMIN PACKARD whose telephone number is (571)270-3440. The examiner can normally be reached on M-R 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612